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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,413	04/06/2001	Robert H. DeBellis	59469/JPW/SHS/MVM	5162

7590 06/16/2003

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EXAMINER
SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/828,413	DeBellis et al.
Examiner	**Art Unit**
Sandra Saucier	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 14, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) *2-9, 11, 12, and 16* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 10, 13-15, and 17-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-19 are pending. Claims 1, 10, 13-15, 17-19 are considered on the merits. Claims 2-9, 11, 12 are withdrawn from consideration as being drawn to a non-elected invention. Claim 16 is drawn to a non-elected species.

Election/Restriction

Claims 2-9, 11, 12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7. The elected species is acyclovir.

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the grounds that the inventions are not independent as defined by MPEP § 802.01 and undue burden has not been established. This is not found persuasive for several reasons explained below.

First, the requirement for a proper restriction is "distinct or independent". See MPEP 806.05 where it is stated that "if they are distinct, restriction may be proper".

Distinctness is an element for consideration when the following categories of invention are presented for examination; product and method of use, product and method of making, apparatus and method of use, etc.. Multiple methods, as in the present case, are always distinct and may also be independent as the practice of one method does not require the practice of another. Even though the methods may share a common element, this does not make the methods "dependent" upon one another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together (MPEP § 806.04, MPEP § 808.01). Thus, the methods are distinct and also independent from one another within the meaning of MPEP § 806.

Further, an undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 17-19 are rejected under 35 U.S.C. 102() as being clearly anticipated by Rodgers *et al.*. [IDS] or Ballas *et al.*. [IDS] in light of Lori *et al.*. [U].

The claims are directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent effective to prevent sickling.

The references are relied upon as explained below.

Rodgers *et al.*. disclose administration of the antiviral compound, hydroxyurea, to patients with sickle cell disease.

Ballas *et al.*. disclose that administration of hydroxyurea improves rheological properties of red cells of patients with sickle cell disease.

Lori *et al.*. disclose that hydroxyurea has antiviral effects; therefore, it can be termed to be an antiviral agent.

Claims 1, 10, 13-15, 17-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lawson *et al.* [V].

The claims are directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent such as acyclovir effective to prevent sickling.

The references are relied upon as explained below.

Lawson *et al.* disclose administering acyclovir to a man with sickle cell trait. The oral dosage is 800 mg x 5. If the person weighed about 100 kg, this would be a dosage of about
400 mg/kg/day.

Because the patient is the same, namely a person afflicted with sickle cell disease, the compound administered is the same, acyclovir, and the amount administered falls within the ranges given in the specification on page 7 for an oral dosage as being an effective dose, the result of the treatment must necessarily, inherently be the same.

It is not relevant to the analysis of the claimed method that the reference makes no mention of (inhibiting, preventing etc.). Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit, where the Federal Circuit upheld a decision that patents licensed to Brassica Protection Products, Inc. are invalid because they are anticipated by the prior art. The patents are for method of growing and eating certain sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that "a prior art reference may anticipate when the claim limitations not expressly found in the that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about (eating) those sprouts, it simply has not invented anything new.".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and

invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, 13-15, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,939,456 [A].

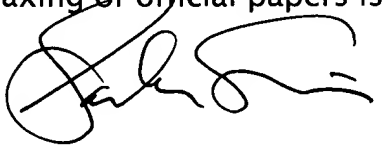
The claims have been discussed above.

The references are relied upon as explained below.

US 5,939,456 discloses administering acyclovir (col. 24, l. 31) to patients with blood disorders such as sickle cell disease (col. 1, l. 3) in combination with compositions that stimulate fetal hemoglobin expression. Although the disclosure makes no mention of acyclovir's activity in the inhibition of the aggregation of hemoglobin S as is instantly disclosed, and is not administered for the same reason as the instant administration, the fact remains that the administration of acyclovir to the patients suffering from sickle cell disease in conjunction with the compositions of the reference which stimulate fetal hemoglobin expression would inherently have the same effect as the instantly claimed effect in the absence of evidence to the contrary.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
June 13, 2003